



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0776]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reclassification Petitions for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0138. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Reclassification Petitions for Medical Devices

(OMB Control Number 0910-0138)--Extension

Under sections 513(e) and (f), 514(b), 515(b), and 520(l) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(e) and (f), 360d(b), 360e(b), and 360j(l)) and part 860 (21 CFR part 860), subpart C, FDA has responsibility to collect data and information contained in reclassification petitions. The reclassification provisions of the FD&C Act allow any person to petition for reclassification of a device from any of the three classes, i.e., I, II, and III, to another class. The reclassification content regulation (§ 860.123) requires the submission of valid scientific evidence demonstrating that the proposed reclassification will provide a reasonable assurance of safety and effectiveness of the device type for its indications for use.

The reclassification procedure regulation requires the submission of specific data when a manufacturer is petitioning for reclassification. This includes a “Supplemental Data Sheet,” Form FDA 3427, and a “General Device Classification Questionnaire,” Form FDA 3429. Both forms contain a series of questions concerning the safety and effectiveness of the device type.

In the Federal Register of March 25, 2014 (79 FR 16252), FDA issued a proposed rule that would eliminate the need for Forms FDA 3427 and FDA 3429. However, because the proposed rule has not been finalized, we continue to include the forms in the burden estimate for this information collection.

The reclassification provisions of the FD&C Act serve primarily as a vehicle for manufacturers to seek reclassification from a higher to a lower class, thereby reducing the regulatory requirements applicable to a particular device type, or to seek reclassification from a lower to a higher class, thereby increasing the regulatory requirements applicable to that device type. If approved, petitions requesting classification from class III to class II or class I provide an alternative route to market in lieu of premarket approval for class III devices. If approved, petitions requesting reclassification from class I or II, to a different class, may increase requirements.

In the Federal Register of March 10, 2015 (80 FR 12642), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received.

The comment refers to changes to the form FDA 3429 as proposed by the commenter in a citizen petition (FDA-2014-P-0283-0001), which was subsequently denied by FDA in a final response letter to the petitioner (FDA-2014-P-0283-0003). Because the proposed changes have already been denied through the citizen petition process, we have not made changes to this information collection based on the comment.

The Center for Devices and Radiological Health (CDRH) has continually maintained contact with industry. Informal communications concerning the importance and effect of reclassification are provided primarily through trade organizations, and via CDRH's Web site. The consensus from the Agency's most recent contact with these trade organizations is that they are in favor of the program. The trade organizations involved are AdvaMed, the Food and Drug Law Institute (FDLI), and the National Electrical Manufacturers Association (NEMA):

AdvaMed, Tara Federici, 1030 15th Street, NW., suite 1100, Washington, DC 20005, 202-452-8240;

Food and Drug Law Institute (FDLI), 1000 Vermont Ave., NW., suite 1200, Washington, DC 20005, 202-371-1420; and

National Electrical Manufacturers Association (NEMA), 1300 North 17th Street, suite 1847, Rosslyn, VA 22209, 703-841-3200.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity	FDA Form Nos.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Supporting data for reclassification petition		6	1	6	497	2,982
Supplemental Data Sheet	3427	6	1	6	1.5	9
General Device Classification Questionnaire	3429	6	1	6	1.5	9
Total						3,000

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on reclassification petitions received in the last 3 years, FDA anticipates that six petitions will be submitted each year. The time required to prepare and submit a reclassification petition, including the time needed to assemble supporting data, averages 500 hours per petition. This average is based upon estimates by FDA administrative and technical staff who: (1) Are familiar with the requirements for submission of a reclassification petition, (2) have consulted and advised manufacturers on these requirements, and (3) have reviewed the documentation submitted.

This document refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The

collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120 and the collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910-0231.

Dated: June 8, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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